

REMARKS OF
CONGRESSMAN HENRY A. WAXMAN
CHAIRMAN, SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
BEFORE THE
2ND ANNUAL GENERIC DRUG CONFERENCE
OCTOBER 28, 1986

CONGRESS WATCHERS HAVE ALREADY SAID THE 99TH CONGRESS THAT JUST ENDED WAS ONE OF THE MOST PRODUCTIVE IN YEARS. I AGREE WITH THAT ASSESSMENT.

TO THE CASUAL OBSERVER, THE 99TH CONGRESS WILL BE REMEMBERED FOR A FEW ISSUES THAT DOMINATED THE NEWSPAPERS IN THE LAST SIX WEEKS: THE TAX REFORM BILL; ARMS CONTROL; AND THE DRUG ABUSE INITIATIVE.

THE EXTENSIVE REPORTING ON THESE ELECTION YEAR ISSUES ELBOWED OUT THE NEWS ABOUT OTHER IMPORTANT LEGISLATION. THERE ARE SEVERAL BILLS THAT I THOUGHT YOU WOULD LIKE TO HEAR ABOUT FIRST HAND.

RECONCILIATION

THE CONGRESS COMPLETED ANOTHER "RECONCILIATION BILL" -- CODE WORDS FOR OUR ANNUAL SEARCH FOR BUDGET SAVINGS TO BRING FEDERAL EXPENDITURES IN LINE WITH THE GRAMM-RUDMAN DEFICIT TARGET. THE BILL RESEMBLED A GARAGE SALE OF FEDERAL ASSETS -- LIKE CONRAIL AND STUDENT LOANS -- MORE THAN A BLUEPRINT FOR FEDERAL BUDGET CONTROL. WE CUT \$11.75 BILLION FROM THE FEDERAL DEFICIT IN FISCAL YEAR 1987.

IN THE MEDICARE PROGRAM, WE CONTINUED TO SQUEEZE PAYMENT RATES TO HOSPITALS AND DOCTORS. AND FOR THE FIRST TIME WE SET STRICT LIMITS ON REIMBURSEMENT FOR HOSPITAL CAPITAL EXPENDITURES THAT WILL SAVE \$1 BILLION IN THREE YEARS.

THOSE ARE QUICK WAYS TO SAVE MONEY. BUT WE ARE FLIRTING WITH DISASTER. HOSPITALS AND DOCTORS CANNOT CONTINUE FOR LONG TO OFFER THE SAME SERVICES TO MEDICARE BENEFICIARIES FOR A DIMINISHING PAYMENT. AND WE DID NOTHING TO ADDRESS THE SHORTCOMINGS OF THE NEW HOSPITAL PAYMENT SYSTEM.

THERE ARE 35 MILLION AMERICANS WHO HAVE NO HEALTH INSURANCE. WHEN THEY NEED HOSPITAL CARE, SOME HOSPITAL HAS TO SERVE THEM. OUR HIGHLY TOUTED MEDICARE PROSPECTIVE PAYMENT SYSTEM DOES NOT RECOGNIZE THE COST OF THEIR FREE CARE.

IN SPIE OF THE DEMANDS FOR IMMEDIATE DEFICIT REDUCTION, THE CONGRESS OCCASIONALLY RECOGNIZES THAT SHORT TERM COSTS CAN MEAN LONG TERM SAVINGS. THE RECONCILIATION BILL EXPANDED MEDICAID COVERAGE TO INCLUDE PRENATAL CARE FOR THE FIRST PREGNANCY OF A POOR WOMAN AND MEDICAL CARE FOR CHILDREN OF POOR FAMILIES UP TO THE AGE OF 5.

SINCE RONALD REAGAN'S FIRST BUDGET, I HAVE DECRIED THE BUDGET ENGINE THAT IS DRIVING OUR NATION'S HEALTH POLICY. WE CANNOT BALANCE

THE BUDGET, NOR CAN WE MEET FUTURE GRAMM-RUDMAN DEFICIT TARGETS ON THE BACKS OF AMERICA'S HOSPITALS AND DOCTORS. IF WE TRY, THE HEALTH CARE THAT THE ELDERLY WANT, AND THE POOR NEED, WILL NOT BE AVAILABLE.

AIDS

NOWHERE ARE THE SHORTCOMINGS OF THIS BUDGET POLICY MORE EVIDENT THAN IN THE ADMINISTRATION'S RESPONSE TO THE AIDS EPIDEMIC. IF THE SIXTIES ARE REMEMBERED FOR THE WAR AND PROTEST; THE LEGACY OF THE EIGHTIES WILL BE THE EPIDEMIC. AND THIS ADMINISTRATION WILL BE REMEMBERED AS IGNORING ALL WARNINGS AND ASKING ONLY THAT THE RESEARCH AND TREATMENT NEEDS BE MET BY SOMEONE ELSE.

FORTUNATELY, THE CONGRESS HAS NOT SHIRKED ITS RESPONSIBILITIES. THIS YEAR, WE SIGNIFICANTLY INCREASED BASIC AIDS RESEARCH AND EDUCATION MONEY, AND, IN ADDITION, TOOK AN IMPORTANT NEW STEP IN THE WAR ON AIDS. WE PROVIDED \$50 MILLION TO DEVELOP NEW DRUGS TO TREAT THE DEADLY DISEASE. WHILE WE ARE PROVIDING AMPLE RESEARCH DOLLARS THAT HOPEFULLY WILL PAY OFF SOMEDAY, THE IMMEDIATE NEEDS FOR TREATMENT WERE BEING IGNORED BY THE FEDERAL GOVERNMENT. WITH THESE NEW FUNDS, NIH WILL TEST CANDIDATE DRUGS AND DESIGN AS-YET-UNDISCOVERED ONES.

VACCINE COMPENSATION

THERE ARE THREE OTHER BILLS THAT WERE ROLLED INTO ONE AND PASSED IN THE LAST HOUR OF THE CONGRESS LAST SATURDAY NIGHT. THE FIRST OF THESE CREATES A CHILDHOOD VACCINE COMPENSATION PROGRAM.

WE TAKE OUR CHILDHOOD VACCINES FOR GRANTED. THEY ARE PUBLIC HEALTH MIRACLES. IN 1952, THERE WERE 57,000 CASES OF PARALYTIC POLIO, LAST YEAR THERE WERE 4.

OUR CONFIDENCE IS SO GREAT THAT ELEMENTARY SCHOOLS REQUIRE VACCINES FOR ENTRY. THAT IS SOUND PUBLIC POLICY. UNFORTUNATELY, VACCINES ARE NOT COMPLETELY SAFE; SO SOME CHILDREN ARE HURT IN THE LINE OF PUBLIC DUTY. EVERY YEAR THERE ARE SERIOUS REACTIONS, INCLUDING MENTAL RETARDATION, PERMANENT DISABILITY AND DEATH.

UNLIKE VETERANS WHO ARE INJURED IN WAR OR WORKERS INJURED ON THE JOB, THESE CHILDREN HAVE NO PLACE TO FILE THEIR GRIEVANCES OR TURN FOR CARE. TO MAKE MATTERS WORSE, THE DRUG COMPANIES THAT MAKE VACCINES ARE NERVOUS. PROGRESS TOWARD NEW AND POTENTIALLY SAFER VACCINES HAS SLOWED.

THE BILL WOULD ESTABLISH A GENEROUS NO-FAULT COMPENSATION SYSTEM TO PAY FOR THE MEDICAL, REHABILITATION, AND EDUCATION COSTS OF THOSE CHILDREN WHO ARE INJURED. IF THE INJURY IS PARTICULARLY SEVERE, THE PROGRAM WOULD PAY FOR LOST EARNINGS OF THE DISABLED CHILD AND FOR THE PAIN AND SUFFERING THAT HE OR SHE ENDURES. IN TURN, THE CHILD'S ABILITY TO SUE THE MANUFACTURER WOULD BE LIMITED.

THE COMPENSATION FUND WILL BE GENERATED BY AN EXCISE TAX ON THE VACCINES. BECAUSE THE TAX COMMITTEES WERE BOGGED DOWN WITH TAX REFORM, THE EXCISE TAX WAS NOT INCLUDED IN THIS YEAR'S BILL. THE TAX WILL BE

CONSIDERED NEXT YEAR. I AM CONFIDENT THAT WITH THE NEW SYSTEM IN PLACE, THE CONGRESS WILL PASS THE NECESSARY EXCISE TAX.

CONGRESS ALSO CREATED A "FAST TRACK" FOR NEW VACCINES. ARMED WITH \$20 MILLION, A CONGRESSIONALLY MANDATED VACCINE "CZAR" AT THE DEPARTMENT OF HEALTH AND HUMAN SERVICES WILL COORDINATE ALL GOVERNMENT ACTIVITY, INCLUDING AT FDA. OUR GOAL IS TO EXPEDITE GOVERNMENT AND JOINT PUBLIC-PRIVATE INITIATIVES IN RESEARCH, DEVELOPMENT, APPROVAL AND PROCUREMENT.

THAT IS THE GOOD NEWS FOR VACCINE-INJURED CHILDREN. THE BAD NEWS IS THAT THE DEPARTMENT OF JUSTICE IS URGING PRESIDENT REAGAN TO VETO THE BILL. ATTORNEY GENERAL MEESE IS REPORTED TO OPPOSE THE NO-FAULT COMPENSATION SYSTEM WE CREATED.

I EXPECT LITTLE MORE FROM THE ATTORNEY GENERAL. I KNOW THE AMERICAN PEOPLE WANT TO HELP THE CHILDREN WHO ARE DAMAGED DOING THEIR SOCIAL DUTY.

MEDICAL MALPRACTICE

THE SECOND PART OF OUR LAST MINUTE BILL IS WHAT WE CALLED "THE BAD DOCTORS' BILL." IT WILL ENCOURAGE PHYSICIANS TO IDENTIFY AND DISCIPLINE OTHER PHYSICIANS WHO ARE INCOMPETENT OR ENGAGE IN UNPROFESSIONAL BEHAVIOR. IT WORKS BY PROVIDING A LIMITED IMMUNITY FROM DAMAGES TO DOCTORS WHO PARTICIPATE IN DISCIPLINARY PROCEEDINGS AGAINST BAD DOCTORS.

IN TURN, DISCIPLINARY ACTIONS AGAINST SUCH DOCTORS MUST BE REPORTED TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES. ALSO REQUIRED TO BE REPORTED ARE MALPRACTICE PAYMENTS.

HOSPITALS WILL BE OBLIGATED TO REQUEST THIS INFORMATION -- WITH THE OBVIOUS BENEFIT THAT DOCTORS WILL NO LONGER BE ABLE TO HIDE THEIR PASTS BY MOVING FROM JURISDICTION TO JURISDICTION.

DRUG EXPORT

THE THIRD PART OF OUR OMNIBUS BILL IS THE LONG-DEBATED "DRUG EXPORT" LEGISLATION. FOR YEARS, U.S. DRUG COMPANIES HAVE CLAIMED THAT U.S. JOBS ARE GOING OVERSEAS TO MAKE THE DRUGS THAT EUROPE APPROVES BEFORE WE DO. EARLIER THIS YEAR THE SENATE PASSED AN EXPORT BILL THAT WENT FAR BEYOND ANY LEGITIMATE CLAIM FOR RELIEF. THE RECENTLY PASSED BILL HAS A MUCH MORE NARROW SCOPE.

A U.S. COMPANY THAT HAS A DRUG IN HUMAN CLINICAL TRIALS WILL BE ALLOWED TO EXPORT THAT DRUG FROM THE U.S., PRIOR TO ITS APPROVAL HERE. EXPORT IS LIMITED TO A STATUTOY LIST OF INDUSTRIALIZED COUNTRIES WITH DRUG APPROVAL SYSTEMS THAT PROTECT THEIR CITIZENS FROM UNSAFE PRODUCTS.

THE BILL DOES NOT PERMIT EXPORT TO DEVELOPING COUNTRIES. AND WE DID ADDRESS THE OFTEN-REPEATED ALLEGATIONS OF MISLABELING AND DUMPING BY U.S. COMPANIES IN THIRD WORLD COUNTRIES. THE PRIMARY HOUSE AND SENATE SPONSORS AGREED TO ASK THE OFFICE OF TECHNOLOGY ASSESSMENT TO

CONDUCT A TWO-YEAR STUDY TO DETERMINE IF U.S. COMPANIES ARE PROPERLY LABELING THE DRUG PRODUCTS THEY SELL OVERSEAS.

GENERIC DRUGS

THAT IS WHAT THE CONGRESS DID. WHAT WE DID NOT DO IS OFTEN AS IMPORTANT. THE ABSENCE OF FURTHER CONGRESSIONAL ACTION ON THE 1984 GENERIC DRUG BILL IS A CLEAR SIGNAL THAT WE LIKE THE RESULTS.

NINE OF THE TOP TEN SELLING BRAND NAME DRUGS ARE NOW AVAILABLE AS GENERICS. HUNDREDS OF NEWLY-APPROVED GENERIC DRUGS ARE CREATING THE ONLY KIND OF WAR CONSUMERS WANT -- PRICE WARS.

THE PRESIDENT PREDICTED A BILLION DOLLARS OF CONSUMER SAVINGS OVER A DECADE. THAT IS CONSERVATIVE. THE 1986 INDUSTRIAL OUTLOOK OF THE COMMERCE DEPARTMENT GOES FURTHER AND SAYS THAT THE GENERIC INDUSTRY WILL SHOW AN INCREASE IN SALES OF MORE THAN A BILLION DOLLARS IN 1986 ALONE, AND THAT BY 1990 ABOUT 30 PERCENT OF ALL PRESCRIPTION DRUGS WILL BE GENERICS.

THIS IS JUST THE BEGINNING OF THE IMPACT OF THE 1984 LAW. AS INSURANCE COMPANIES, HOSPITALS, AND PUBLIC PROGRAMS BECOME FAMILIAR WITH POSSIBLE SAVINGS, MANY WILL BEGIN TO SHIFT TO GENERIC PRODUCTS. TOTAL ACCEPTANCE BY THE PUBLIC IS INEVITABLE.

ONLY THE BRAND NAME COMPANIES HOLD OUT. THEY CRITICIZE GENERICS WITH THE 1980'S SOPHISTICATED VERSION OF THE 1960'S DIATRIBE AGAINST UNSAFE AND INEFFECTIVE GENERICS.

THEIR ANTI-GENERIC CAMPAIGN IS DISINGENUOUS AND HURTS THE PUBLIC. THEIR CREDIBILITY IS AT STAKE, BECAUSE THEY MAKE GENERICS IN PRIVATE WHILE THEY LAMBAST THEM IN PUBLIC.

I DO NOT BELIEVE THAT CONSUMERS, INSURANCE COMPANIES, HMOs, HOSPITALS OR GOVERNMENT ARE SO GULLIBLE. ON ONE HAND, THE BRAND NAME COMPANIES TELL US THAT GENERICS ARE NOT TRUSTWORTHY. ON THE OTHER, THEY RAISE THEIR PRICES AT UNPRECEDENTED RATES. THE PUBLIC AND THE HEALTH CARE SYSTEM ARE THE LOSERS FROM THIS DOUBLE DOSE OF CORPORATE GREED.

THE ELDERLY USE THIRTY PERCENT OF THE PRESCRIPTION DRUGS IN THE U.S., BUT MEDICARE DOES NOT PAY FOR DRUGS. MOREOVER, NATIONWIDE DATA SHOW THAT 80 PERCENT OF THE DRUGS IN THE U.S. ARE BOUGHT WITHOUT ANY INSURANCE, LEAVING CONSUMERS WITH THE FULL BURDEN OF INCREASED COSTS.

AND CONSUMER COSTS HAVE SKYROCKETED. AT MY SUBCOMMITTEE'S JULY 15, 1985 HEARING, WE DOCUMENTED THE UNPRECEDENTED RISE. BETWEEN 1981 AND JUNE, 1985, THE CPI INCREASED 23%. DURING THE SAME TIME, MANUFACTURER WHOLESALE PRICES ROSE 56%. MANY OF THE TOP-SELLING DRUGS ROSE EVEN FASTER.

THESE ENORMOUS INCREASES ARE CONTINUING IN 1986. IT IS MY UNDERSTANDING THAT DOUBLE DIGIT PRICE INCREASES ARE STILL COMMONPLACE. MY SUBCOMMITTEE WILL BE CONDUCTING ANOTHER HEARING ON PRICES IN

NOVEMBER OR DECEMBER OF THIS YEAR.

BRAND NAME COMPANIES HAVE NOT RESPONDED TO NEW MARKET PRESSURES WITH GOOD-FAITH FOR THE AMERICAN PEOPLE. THEIR ACTIONS DO NOT JUSTIFY THE TAX CREDITS AND PATENT EXTENSIONS CONGRESS EXTENDED THEM IN 1981 AND 1984. AT A TIME WHEN MUCH OF THE HEALTH CARE INDUSTRY IS UNDER SEVERE COST CONSTRAINTS, UNPRECEDENTED PRICE INCREASES AND AN ANTI-GENERIC CAMPAIGN ARE A SOURCE OF GREAT CONCERN.

IN 1986 CONGRESS CONSIDERED, BUT FAILED TO PASS LEGISLATION FOR GENERIC ANIMAL DRUGS. THE BILL WAS MODELED AFTER THE 1984 LAW. IT WOULD HAVE CREATED A GENERIC APPROVAL SYSTEM FOR ANIMAL DRUGS AND PROVIDED PATENT TERM RESTORATION FOR BRAND NAME DRUGS. THE BILL FAILED IN THE SENATE BECAUSE THE BRAND NAME COMPANIES INSISTED ON SPECIAL TRANSITION RULES TO PROTECT DRUGS ALREADY ON THE MARKET.

I EXPECT SIMILAR LEGISLATION TO BE CONSIDERED AGAIN IN THE NEXT CONGRESS.

NEXT YEAR

ALTHOUGH THE OMNIBUS BILL WE PASSED ON SATURDAY HAS NOT YET GONE TO THE PRESIDENT FOR HIS SIGNATURE, IT IS ALREADY TIME TO BEGIN THINKING OF THE NEXT CONGRESS.

BUDGET PRESSURE IS NOW A FACT OF CONGRESSIONAL LIFE. THE CRITICS OF THIS YEAR'S RECONCILIATION BILL POINTED OUT THAT IT CONTAINED ONE-TIME SAVINGS. THEY WARNED THAT IT MADE NEXT YEAR'S GRAMM-RUDMAN DEFICIT TARGET OF \$108 BILLION VIRTUALLY UNREACHABLE.

WE CAN MEET THE 1988 DEFICIT TARGET, BUT IT WILL TAKE EITHER A ROBUST ECONOMY OR TAX INCREASES OR SPENDING CUTS THAT ARE UNPRECEDENTED. IF THE DIFFERENCE IS FOUND IN SOCIAL SPENDING, FDA'S BUDGET AND HOSPITAL AND DOCTOR PAYMENT RATES WILL BE IN SERIOUS JEOPARDY.

THERE ARE SEVERAL AREAS OF LEGISLATIVE ACTIVITY NEXT YEAR THAT I ASSUME ARE OF INTEREST TO YOU.

IF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES DOES NOT RECREATE THE MAXIMUM ALLOWABLE COST PROGRAM IN THE NEXT THREE MONTHS, CONGRESS WILL. THE MAC PROGRAM WAS MEDICAID'S WAY TO LIMIT REIMBURSEMENT TO PHARMACISTS TO THE COST OF GENERIC DRUGS, WHEN THEY ARE AVAILABLE.

IN 1983, THE DEPARTMENT OF HHS SUSPENDED THE MAC PROGRAM, CIIING PROBLEMS IN SETTING FAIR REIMBURSEMENT LEVELS AND MINIMAL SAVINGS THAT MADE THE PROGRAM UNIMPORTANT. I AGREED IN 1983, BUT THE 1984 GENERIC DRUG LAW CHANGED THINGS. THE REAGAN ADMINISTRATION HAS WASTED MILLIONS OF DOLLARS IN THE LAST TWO YEARS BY DELAYING THE SUCCESSOR PROGRAM.

FURTHER DISCUSSION IS UNNECESSARY. FURTHER DELAY RAISES SERIOUS QUESTIONS ABOUT THE MOTIVATIONS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES. ARE THEY PROTECTING THE BRAND NAME COMPANIES OR THE FEDERAL GOVERNMENT?

IF NEW REGULATIONS ARE NOT FORTHCOMING, MY LEGISLATION WILL BE.

I INTEND TO PUSH AHEAD WITH MY BILL TO REFORM MEDICAL DEVICE REGULATION. CURRENT LAW DEMANDS FAR MORE THAN FDA'S MEAGER RESOURCES CAN DELIVER. IT IS TIME TO SET NEW PRIORITIES. IT IS TIME TO FOCUS FDA'S ATTENTION ON THOSE MATTERS WITH THE GREATEST IMPACT ON CONSUMER HEALTH AND SAFETY.

I EXPECT CONGRESSMAN DINGELL, THE CHAIRMAN OF THE ENERGY AND COMMERCE COMMITTEE, TO REINTRODUCE HIS DRUG DIVERSION BILL. THAT IMPORTANT CONSUMER LEGISLATION BOGGED DOWN IN AN END-OF-THE-SESSION DISPUTE WITH THE PHARMACEUTICAL COMPANIES OVER THE CONTROL OF FREE DRUG SAMPLES.

A NUMBER OF PROBLEMS WITH THE ORPHAN DRUG ACT HAVE BEEN IDENTIFIED AND MUST BE ADDRESSED. WE DESPARATELY NEED ADDITIONAL GRANT FUNDS FOR RESEARCH ON DRUGS THAT COMPANIES WILL NOT SPONSOR.

WE ALSO MUST CLARIFY WHO HAS THE RIGHT TO RECEIVE THE SEVEN YEARS OF MARKET EXCLUSIVITY. UNDER CURRENT LAW, WHEN TWO COMPANIES SIMULTANEOUSLY DEVELOP AN ORPHAN DRUG, THE FIRST COMPANY THAT IS APPROVED GETS THE RIGHT TO MARKET THE DRUG AND THE SECOND GETS NOTHING. WE MUST FIND A WAY TO REWARD ORPHAN DRUG DEVELOPMENT THAT DOES NOT DISCOURAGE INDEPENDENT AND SIMULTANEOUS WORK BY A SECOND COMPANY.

AND LAST, THE TIME HAS COME TO REFOCUS OUR REGULATION OF NURSING HOMES. THE INSTITUTE OF MEDICINE HAS JUST COMPLETED A TWO YEAR, ADMINISTRATION-SPONSORED STUDY OF NURSING HOME REGULATION. I INTEND TO INTRODUCE LEGISLATION IN JANUARY WHICH REFLECTS THE STUDY'S FINDINGS.

FOR YEARS WE HAVE ATTEMPTED TO PROTECT NURSING HOME RESIDENTS BY AUDITING THEIR PHYSICAL SURROUNDINGS. A BETTER APPROACH IS TO FOCUS ON PATIENT OUTCOME.

NEW REQUIREMENTS, EVEN IF WE ELIMINATE SOME OF THE OLD, WILL COST MONEY. I BELIEVE OUR ELDERLY DESERVE NOTHING LESS THAN THE ASSURANCE THAT THEIR NURSING HOME STAY WILL IMPROVE THEIR CONDITION. IF THAT TAKES MORE MONEY, I AM READY TO SPEND IT.

CLOSING

AS YOU CAN SEE, THE 100TH CONGRESS WILL BE MEMORABLE FOR MORE THAN ITS NUMBER. FROM BILLIONS IN BUDGET SAVINGS TO EPIDEMIC CONTROL TO NEW DRUG DEVELOPMENT, LEGISLATION WILL BE COMING FAST AND FURIOUS. FOR THOSE INTERESTED IN THE HEALTH CARE MARKETPLACE IT WILL BE A DECISIVE YEAR FOR POLICY AND PRACTICAL ECONOMICS.

THANK YOU.